

REMARKS

Claims 1-9 had been rejected in Paper #6. Claims 1-8 are now cancelled. Claim 9 is pending in the application, in amended form. Claims 10-16 have been added, and relate to claims 2-8, but are in method of use form. Support for the amendments can be found on page 2, lines 7-12 of the specification, Example 1, Example 2 and Example 3, at page 8, line 21.

Applicants wish to thank the Examiner for the courtesy extended at the interview on 22 May 2003. Applicants acknowledge that the Interview Summary accurately reflects the substance of the interview.

Claim Rejections - 35 U.S.C. §103

(1) Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feery et al., Med. J. Aust. 1:128-30 (Feery) in view of Edwards et al, Ped. Vol. 96 supp., pp. 548-57 (1995) for reasons outlined in Paper #6. Applicants note that claim 1 has been cancelled, but will address the rejection with respect to claim 9, as amended.

Edwards et al. disclose 13 acellular DTPa vaccines, with different amounts of antigens (i.e., D, T and Pa) and various combinations of acellular pertussis antigens (Pa) (i.e., containing one or more of the following: PT, FHA, FHM, PRN). It is noted that all the vaccines disclosed by Edwards et al. are for primary immunization of infants (under 1 year of age), and not for booster vaccination of adolescents and/or adults.

Feery et al disclose a reduced dose DT vaccine for primary immunization (three doses) and also for boosting of individuals who were previously exposed to diphtheria and tetanus, either naturally or via immunization. Neither of the cited references, however, disclose boosting of adolescents or adults with pertussis, or a combination diphtheria-tetanus-pertussis vaccine. Moreover, Applicants submit that none of the cited references provide the motivation to arrive at the claimed invention.

Applicants respectfully submit that the claimed invention would not be considered obvious to one of skill in the art for the following reasons:

(a) Pertussis infection was generally considered a significant public health risk for children, rather than adults and adolescents. Thus, after children received their course of primary immunizations for DTPa (3-5 inoculations), the need for additional immunization was not clearly evident, at least at the time of the instant invention. The public perception to adult and adolescent immunization is slowly changing (see, e.g., Campins-Marti et al., *Vaccine*, 20: 641-646 (2002) copy enclosed).

(b) Whole cell and acellular (DTPa) vaccines are not approved for people over 7 years of age (See, Vaccine Information Statement, DTaP, 7/30/01, U.S. Dept. of Health and Human Services – copy enclosed), because of the increasing number of adverse events in the 7 and older population.

(c) In contrast to the claimed invention, the cited art does not teach a composition of pertussis antigens (i.e., specific proteins and their dosage) for use as a booster vaccine in children over 7 years of age.

(d) Applicants note that reactogenicity in adolescents with the claimed DTPa vaccine was significantly less *compared to the booster vaccine without pertussis* (see Figure 10 - under Redness, and Swelling).

Therefore, given the above remarks, Applicants respectfully submit that the claimed invention is not obvious over the teachings of Edwards et al. with those of Feery et al. For those reasons, Applicants respectfully request that this rejection be withdrawn.

(2) Claim 2 was rejected under 35 U.S.C. 103(a) as being unpatentable over Feery in view of Edwards. Applicants note that claim 2 has been cancelled, so technically this rejection is moot. However, Applicants respectfully submit that newly added claim 10 would be patentable over the cited references for the reasons note in (1) above.

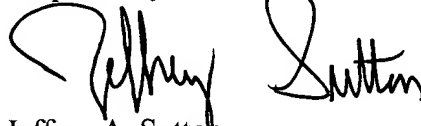
(3) Claims 1, 3-8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feery, and Edwards and further in view of Petre et al., PCT/EP93/01276 (Petre) and Eckhardt et al. U.S. Patent Number 5,895,655 (the '655 patent) for reasons outlines in Paper #6.

- Claims 1, 3-8 have been canceled. However, Applicants will address the rejection with respect to claim 9, as amended.

Applicants note that *Petre teaches a Hepatitis B vaccine* that may be combined with one or more other antigens, such as, Hepatitis A (HA), D, T, Pa, Hib and polio. Eckhardt et al, teach a desire in the art to combine antigens in order to reduce the number of injections needed to provide protection against various infections. Neither Petre nor Eckhardt teach a low dose vaccine comprising DTPa, for any use. Thus for reasons identified above, Applicants respectfully submit that it would not have been obvious to combine the teachings of Feery and Edwards with those of Petre and Eckhardt., for none of the cited references teach a DTPa booster vaccine for adolescents and adults.

Applicants respectfully submit that the aforementioned amendments and remarks are fully responsive to the Office Action and request reconsideration of the rejections stated therein. The Examiner is invited to contact Applicants' undersigned at the telephone number provided below if such might facilitate allowance of the pending claims.

Respectfully submitted,



Jeffrey A. Sutton
Attorney for Applicants
Registration No. 34,028

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone (610) 270-6316
Facsimile (610) 270-5090
N:\jas\pto\B45096C1\B45096C1 Response.doc